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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,930	05/24/2001	Ronald Berenson	980034.415	1690

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EXAMINER	
EWOLDT, GERALD R	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 01/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/864,930	BERENSON	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, response, and 1.132 declaration of Inventor Berenson, filed, 10/18/04, are acknowledged.

2. Claims 6-11 are pending and under examination.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless --.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (f) he did not himself invent the subject matter sought to be patented.

4. Claims 6-9 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by PR Newswire (07 December 1998) as evidenced by U.S. Patent No. 5,858,358.

As set forth previously, PR Newswire teaches a method for the restoration or enhancement of immune function in an immunocompromised or immunosuppressed subject (terminal non-Hodgkins lymphoma patients) wherein the subject is immunocompromised due to chemotherapy, comprising administering autologous T cells activated with anti-CD3 and anti-CD28 antibodies (see entire document). The '358 patent teaches that the method of activating T cells employing an anti-CD3 antibody and an anti-CD28 antibody immobilized on a single surface in *cis* was well known in the art at the time of the invention (see particularly Examples 4 and 8).

Applicant's arguments, filed 10/18/04, have been fully considered but they are not persuasive. Applicant argues that the reference does not teach the newly added limitations to the claims, i.e., restoring or enhancing immune function in an artificially induced immunocompromised or immuno-suppressed subject, wherein said restoring or enhancing immune function comprises an increase in neutrophil counts.

The reference teaches that the Xcellerate™ process (the process of the claimed method) was used to stimulate an immune response in non-Hodgkin's lymphoma patients who were no longer responsive to chemotherapy. It is well-established that chemotherapy patients become immunosuppressed. For example, it is well-known that CHOP treatment (a combination of cyclophosphamide, doxorubicin, vincristine, and prednisone), a standard treatment for non-Hodgkin's lymphoma, is extremely immunosuppressive (see Leporrier (2004), Abstract enclosed). Thus, the reference meets the newly claimed limitation of

treating "artificially induced" immunosuppresssion. Regarding increasing neutrophil counts, this new limitation comprises no more than a description of an inherent property of the treatment itself, i.e., the use of the Xcellerate™ process on the patients of the reference would have resulted in the same increase.

5. Claims 6-9 stand rejected under 35 U.S.C. 102(b) as being clearly anticipated by Henderson (21 December 1998) as evidenced by U.S. Patent No. 5,858,358.

As set forth previously, Henderson teaches a method for the restoration or enhancement of immune function in an immunocompromised or immunosuppressed subject (terminal non-Hodgkins lymphoma patients) wherein the subject is immunocompromised due to chemotherapy, comprising administering autologous T cells activated with anti-CD3 and anti-CD28 antibodies (see entire document). The '358 patent teaches that the method of activating T cells employing an anti-CD3 antibody and an anti-CD28 antibody immobilized on a single surface in *cis* was well known in the art at the time of the invention (see particularly Examples 4 and 8).

See the Examiner's response in Section 4 above.

6. Claims 6-11 stand rejected under 35 U.S.C. § 102(f) because the Applicant did not invent the claimed subject matter.

As set forth previously, in PR Newswire (07 December 1998), the reference of the rejection in section 3, above it is stated that to overcome the problem of inadequate T cell signaling seen in conditions such as cancer, Xcyte founders Carl June and Craig Thompson "invented a process using monoclonal antibodies attached to beads that bind to CD3 and CD28 receptors to provide costimulatory signals to T cells." While also mentioned in the reference as president of the company, Inventor Berenson is not mentioned as a coinventor, much less the *sole* inventor, of the process of the instant claims set forth in the reference.

Applicant's arguments, filed 10/18/04, have been fully considered but they are not persuasive. Applicant again argues that the reference does not teach the newly added limitations to the claims, i.e., restoring or enhancing immune function in an artificially induced immunocompromised or immuno-suppressed subject, wherein said restoring or enhancing immune function comprises an increase in neutrophil counts. Inventor Berenson has also submitted a 1.132 declaration stating that he alone invented the method of the instant claims.

See the Examiner's response in Section 4 above.

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 10 and 11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over PR Newswire (07 December 1998) in view of U.S. Patent No. 5,858,358 and U.S. Patent No. 5,861,406.

As set forth previously, PR Newswire (07 December 1998) has been discussed above.

The reference teaching differs from the claimed invention only in that it does not teach the use of the claimed method for the treatment of immunosuppression due to radiation treatment or due to treatment with an immunosuppressant.

The '358 patent teaches that the use of the method of the instant claims can be used in therapeutic situations where it would be desirable to upregulate or enhance an immune response (see particularly column 20, lines 33-49).

The '406 patent teaches that cancer chemotherapy and ionizing radiation can be very immunosuppressive (see particularly column 10, lines 35-40).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a method for the restoration or enhancement of immune function in an immunocompromised or immunosuppressed subject wherein the subject is immunocompromised due to chemotherapy, radiation treatment or due to treatment with an immunosuppressant, said method comprising administering autologous T cells activated with anti-CD3 and anti-CD28 antibodies, as taught by PR Newswire (07 December 1998). One of ordinary skill in the art at the time the invention was made would have been motivated to use the method of PR Newswire (07 December 1998) for the treatment of any type of immunosuppression, including the well-known immunosuppression due to chemotherapy or radiation treatment (as taught by the '406 patent) or the use of immunosuppressants, given the teachings of the '358 patent that the method taught therein could be used to upregulate or enhance an immune response in any therapeutic situation wherein said up regulation or enhancement would be desirable, e.g., immunosuppression.

Applicant's arguments, filed 10/18/04, have been fully considered but they are not persuasive. Applicant again argues that the reference does not teach the newly added limitations to the claims, i.e., restoring or enhancing immune function in an artificially induced immunocompromised or immuno-suppressed

subject, wherein said restoring or enhancing immune function comprises an increase in neutrophil counts.

See the Examiner's response in Section 4 above.

9. Claims 10 and 11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Henderson (21 December 1998) in view of U.S. Patent No. 5,858,358 and U.S. Patent No. 5,861,406.

As set forth previously, Henderson (21 December 1998), U.S. Patent No. 5,858,358 and U.S. Patent No. 5,861,406 have been discussed above.

The primary reference teaching differs from the claimed invention only in that it does not teach the use of the claimed method for the treatment of immunosuppression due to radiation treatment or due to treatment with an immunosuppressant.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a method for the restoration or enhancement of immune function in an immunocompromised or immunosuppressed subject wherein the subject is immunocompromised due to chemotherapy, radiation treatment or due to treatment with an immunosuppressant, said method comprising administering autologous T cells activated with anti-CD3 and anti-CD28 antibodies, as taught by Henderson (21 December 1998). One of ordinary skill in the art at the time the invention was made would have been motivated to use the method of Henderson (21 December 1998) for the treatment of any type of immunosuppression, including the well-known immunosuppression due to chemotherapy or radiation treatment (as taught by the '406 patent) or the use of immunosuppressants, given the teachings of the '358 patent that the method taught therein could be used to upregulate or enhance an immune response in any therapeutic situation wherein said up regulation or enhancement would be desirable, e.g., immunosuppression.

See the Examiner's response in Section 4 above.

10. Claims 1-11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,858,358 in view of U.S. Patent No. 5,861,406.

As set forth previously, U.S. Patent No. 5,858,358 and U.S. Patent No. 5,861,406 have been discussed above.

The primary reference teaching differs from the claimed invention only in that it does not teach the use of the claimed method for the treatment of immunosuppression due to chemotherapy, radiation treatment, or due to treatment with an immunosuppressant.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a method for the enhancement of immune function in an immunosuppressed subject wherein the subject is immunosuppressed due to chemotherapy, radiation treatment or due to treatment with an immunosuppressant, said method comprising administering autologous T

cells activated with *cis* immobilized anti-CD3 and anti-CD28 antibodies, as taught by the '358 patent. One of ordinary skill in the art at the time the invention was made would have been motivated to use the method the '358 patent for the treatment of any type of immunosuppression, including the well-known immunosuppression due to chemotherapy or radiation treatment (as taught by the '406 patent) or the use of immunosuppressants, given the teachings of the '358 patent that the method taught therein could be used to upregulate or enhance an immune response in any therapeutic situation wherein said up regulation or enhancement would be desirable.

See the Examiner's response in Section 4 above.

11. The following are new grounds for rejection necessitated by Applicant's amendment.

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 6-11 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A method for restoring or enhancing immune function in an artificially induced immunocompromised or immuno-suppressed subject, wherein said restoring or enhancing immune function comprises an increase in neutrophil counts (Claim 6).

Applicant indicates that support for the new limitation can be found at page 7, lines 6-11 of the specification.

A review of the specification fails to reveal support for the generic "artificially induced" immunocompromise or immunosuppression of the claim. At page 6, lines 15-27, the specification discloses only various primary and secondary causes of immunodeficiency. Regarding the limitation of "an increase in neutrophil counts", the specification discloses at page 7 that "granulocyte transfusions and drugs such as Neuupogen [sic]"

increase neutrophil counts, whereas the present invention would "reduce the risk of infections in patients that suffer from lymphocyte dysfunction and/or decreased lymphocyte counts".

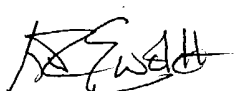
13. No claim is allowed.

14. Applicant's amendment or action necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Inquiries of a general nature may also be directed to the Technology Center 1600 Receptionist at (571) 272-1600.

G.R. Ewoldt, Ph.D.
Primary Examiner
Technology Center 1600



1/5/05

G.R. EWOLDT, PH.D.
PRIMARY EXAMINER